K063852

510(k) Summary

Submitter's Name, Address, Contact

Home Access Health Corporation ("HAHC")
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NOV 09 2007

Contact Person: Mary Vogt, Vice President
Date Prepared: 21 December 2006
Device Name:

Proprietary Name:	**accessa Cholesterol Panel**
Common Name:	Capillary blood self-collection and transportation system for Total Cholesterol, HDL-Cholesterol, Triglycerides, and Calculated LDL-Cholesterol.
Classification Names:	Capillary blood self-collection and transport system for the in-vitro testing of: Cholesterol (21CFR 862.1175) HDL Cholesterol (21CFR 862.1475) Triglycerides (21CFR 862.1705) LDL Cholesterol (21CFR 862.1475)

Predicate Devices:

Predicate Device: Safe At Home Cholesterol Profile K012221
manufactured by BIOSAFE Laboratories, Inc.

Predicate Test Methods:

- Total Cholesterol: Amresco Cholesterol Reagent Assay K891922
- HDL Cholesterol: Wako L-Type HDL-C Reagent Assay K801834
- Triglycerides: Roche Triglycerides K801298

Device Description:

The accessa Cholesterol Panel incorporates the use of two separately regulated products.

- The Home Access Micro Serum Specimen (MSS) Collection Kit (a Class I Medical Device listed with the FDA effective February 19, 2003, and manufactured under the Quality System Regulations) and
- The Home Access Health Corporation (HAHC) Clinical Chemistry Laboratory Lipid Profile Test Methods (Regulated under CLIA number 14D0981820).

Collection Kit Description:

The Home Access Micro Serum Specimen Collection Kit ("MSS collection kit"), (Class I Medical Device CFR 21 Part 864.3250, registered February 19, 2003) is intended to facilitate in vitro diagnostic laboratory testing of fingerstick blood samples for a variety of clinical chemistry assays. This MSS collection kit includes a collection cassette, storage pouch and prepaid mailer along with all the materials necessary to self-collect a capillary blood sample into the blood collection/transportation cassette. The cassette is packaged along with patient/customer information and transported to the certified clinical laboratory for lipid profile testing. In its final configuration, the accessa Cholesterol Panel kit is comprised of:

- Blood collection/transportation cassette
- Sample Return Pouch with Desiccant
- 2 Safety lancets
- Gauze pad
- Adhesive bandage
- Instructions for use
- Brochure: "What you need to know to keep your heart healthy"
- Prepaid US Mail return mailer
- Informed Consent Form
- Outer Box

Testing Service Description:

- The patient/customer follows the directions to self-collect a capillary blood sample (approximately 100 micro liters), package and mail the sample to a certified clinical laboratory for analysis using FDA-cleared reagent and analysis systems. Once the dried sample is received in the laboratory, it is accessioned, labeled and eluted into a usable serum sample. Once eluted, the sample can be assayed as a diluted serum sample using US FDA-cleared reagents. All testing is done via the Roche Cobas Mira Plus chemical analyzer and utilizes the software approved for use in the testing instrument (K920402). The clinical laboratory is located at Home Access Health Corporation.

Indications for Use:

The accessa Cholesterol Panel is intended for in vitro, quantitative determination of Total Cholesterol, HDL-Cholesterol, Triglycerides and calculated LDL-Cholesterol in dried micro-serum samples ("Cholesterol Panel"). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases. The Cholesterol

Panel is not intended for use on neonates. LDL-Cholesterol cannot be determined where the triglycerides value is greater than 400 mg/dL.

Comparison to Predicate Devices:

The accessa Cholesterol Panel is substantially equivalent to the Safe At Home Cholesterol Profile K012221 manufactured by BIOSAFE Laboratories, Inc, as well as the laboratory methods listed below. Both the accessa Cholesterol Panel and the Safe At Home Cholesterol Profile kits provide the patient a method to collect a sample at home, mail it to a clinical laboratory, and later receive a report showing Total Cholesterol, HDL, Triglycerides, and Calculated LDL-Cholesterol. The only significant difference is the accessa Cholesterol Panel kit separates the serum from the blood whereas the Safe At Home kit collects whole blood.

The accessa Cholesterol Panel has technological characteristics that are substantially equivalent to that of the predicate devices listed above. The accessa Cholesterol Panel provides components that permit collection, storage, and transportation of a dried serum blood sample to a certified clinical laboratory for analysis using FDA-Cleared or Exempt laboratory reagent and analysis systems. All predicate and current kits are intended for the in vitro diagnostic laboratory determination of lipid profile analytes. The laboratory analyses used in conjunction with the accessa Cholesterol Panel utilize these test methods:

Total Cholesterol: Amresco Cholesterol Reagent Assay K891922
HDL Cholesterol: Wako L-Type HDL-C Reagent Assay K801834
Triglycerides: Roche Triglycerides K801298

Results of clinical trials show that self-collected capillary samples onto the accessa Blood Collection Cassette provide results that are substantially equivalent to venous (serum) results for Total Cholesterol, HDL-Cholesterol and Triglycerides when analyzed using Home Access Health Laboratories modified analytical methods.

Performance Studies:

The accessa Cholesterol Panel was validated using data from bench studies and from the formal clinical study conducted independently by LMARC Research Center in Louisville, KY between March 2006 and May 2006. The formal clinical study included self-collected capillary samples and professionally collected capillary samples using the blood collection/transportation cassette. Additionally, venipuncture samples were collected from each study subject to allow for comparison of serum lipid results with those obtained from capillary samples. All samples were express-shipped to the clinical laboratory. Each self-collected and each professionally-collected capillary sample was tested using the proprietary algorithm and results were compared to venipuncture sample results.

Conclusion:

The results of clinical trials demonstrated that self-collected capillary samples, tested using the HAHC proprietary testing algorithm, are substantially equivalent to venous (serum) results for Total Cholesterol, HDL-Cholesterol, Triglycerides and calculated LDL-Cholesterol. Analysis of data from both clinical and non-clinical testing shows that the accessa Cholesterol Panel is as safe and effective as the predicate device(s) and has no new indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Home Access Health Corporation
c/o Ms. Karen L. Hanson
Director, Regulatory Affairs/Quality Assurance
2401 West Hassell Road, Suite 1510
Hoffman Estates, IL 60169

NOV 0 9 2007

Re: k063852
Trade/Device Name: accessa Cholesterol Panel
Regulation Number: 21 CFR §862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA, LBS, JGY, CHH
Dated: October 30, 2007
Received: October 31, 2007

Dear Ms. Hanson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k063852

Device Name: accessa Cholesterol Panel

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Prescription Use X AND/OR Over-the-Counter Use X
(Part 21 CFR Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
...on Sign-Off

...ice of In Vitro Diagnostic Device
...luation and Safety

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